PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant(s):	Mangiardi et al.	
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APPEAL BRIEF UNDER 37 CFR § 41.37

This Appeal Brief is filed pursuant to the "Notice of Appeal to the Board of Patent Appeals and Interferences" filed March 4, 2009.

1. ***Real Party in Interest.***

The real party in interest in this appeal is Merit Medical Systems, Inc.

2. ***Related Appeals and Interferences.***

None.

3. ***Status of Claims.***

The present appeal involves Claims 1, 3-8, 10-24, 37, 39-42, 45, 46, 48-50, 52-54, 56, and 57, which are under final rejection as set forth by the Office Action mailed October 14, 2008. The claims at issue are set forth in the attached Claims Appendix.

4. ***Status of Amendments.***

Claims 1, 3-8, 10-24, 37, 39-42, 45, 46, 48-50, 52-54, 56, and 57 have not been amended following the final Office Action mailed October 14, 2008.

5. ***Summary of Claimed Subject Matter.***

Embodiments of the present invention provide devices that allow a user to calculate the length and diameter of a suitable interventional prosthesis as well as the height and length of a stenosis during the same exploratory surgery, as well as methods for measuring a target segment of a lumen of a patient so as to select a suitable interventional prosthesis.

Independent Claims 1, 7, 24, and 37 each recite a device (100) that includes an exterior conduit (130) longitudinally extending between proximal and distal ends, wherein the exterior conduit has measurement markers (160) formed on a portion thereof configured to provide information regarding a length of the target segment (p. 8, lines 16-20; p. 10, lines 27-28; FIGS. 1, 2, 3, 7, and 14). Independent Claims 1, 7, 24, and 37 further recite that the device includes an interior conduit (180) longitudinally extending between proximal (190) and distal (200) ends, disposed within the exterior conduit (130), and displaceable with respect to the exterior conduit (p. 8, lines 16-23; p. 8, line 25 – p. 9, line 7; FIGS. 2, 4, 6, 8-10, 15, and 17). Independent Claims 1, 7, and 24 further recite that the interior conduit (180) includes a depth marking mechanism (210) visible through a portion of the exterior conduit (130) (p. 8, lines 23-25; p. 11, lines 19-23; FIG. 3, 4, 7, and 14-17).

In addition, independent Claims 1, 7, 24, and 37 recite a measurement assembly (240) including at least two legs (250, 300) having distal (260, 310) and proximal (270, 320) ends and inward facing (280, 330) and lumen facing (290, 340) surfaces, wherein the inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit (130) (p. 9, lines 8-18; p. 10, lines 16-26; FIGS. 5-13 and 16-18). In addition, Claims 1, 7, 24, and 37 recite that the legs (250, 300) are coupled with each other proximal the distal ends (260, 310) thereof, and the measurement assembly (240) is also coupled about the distal end (200) of the interior conduit (180) (p. 9, lines 8-14; FIGS. 2, 5-8, and 15-18).

Claims 1 and 37 further recite that the lumen facing surface of each of the legs (250, 300) includes a plurality of measurement markers (350) and that the exterior conduit (130) is configured to engage the measurement markers (350) of the legs to provide an indication of a diameter of the target segment (p. 9, lines 21-23; p. 10, lines 3-15; FIGS. 9-11 and 18). Similarly, Claims 7 and 24 recite that the lumen facing surface of each of the legs (250, 300) includes a plurality of measurement markers (350) that are configured to provide information regarding a diameter of the target segment (p. 9, lines 21-23; p. 10, lines 3-15; FIGS. 9-11 and 18).

Furthermore, independent Claims 1, 7, 24, and 37 recite a handle (220) that is operatively connected with the measurement assembly (240), wherein the handle includes means for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open configuration. Thus, Claims 1, 7, 24, and 37 include a means-plus-function limitation under 35 U.S.C. §112, sixth paragraph. The present application discloses that the structure corresponding to the function of opening and closing the measurement assembly (240) may include a trigger mechanism (230), such as a slide-gauge mechanism, for opening and closing the measurement assembly (p. 8, line 16 – p. 9, line 7; FIGS. 1-10 and 12-17).

Independent method Claims 7 and 24 also recite introducing the device (100) into an appropriate anatomical orifice of a patient and delivering the device adjacent to a target segment of a lumen within the patient (p. 3, lines 5-21; p. 7, line 18 – p. 8, line 2). Claim 7 further recites measuring the length of the target segment within the patient (p. 3, lines 16-21; p. 7, lines 18-22; p. 11, lines 19-23) and displacing the exterior conduit (130) and measurement assembly (240) relative to one another such that the exterior conduit (130) engages the measurement markers (350) of the legs (250, 300) to provide an indication of a diameter of the target segment (p. 9, lines 21-23; p. 10, lines 3-15; FIGS. 9-11 and 18). Moreover, Claim 24 recites the step of measuring the diameter of the target segment of the lumen within the patient (p. 3, lines 16-21; p. 7, lines 18-22; p. 11, lines 19-23), wherein measuring a diameter of the target segment comprises displacing the exterior conduit (130) and measurement assembly (240) relative to one another

such that the exterior conduit (130) engages the measurement markers (350) of the legs (250, 300) (p. 9, lines 21-23; p. 10, lines 3-15; FIGS. 9-11 and 18).

6. ***Grounds of Rejection to be Reviewed on Appeal.***

a) Claims 5, 12, and 41 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

b) Claims 1, 3-8, 10-24, 37, 39-42, 45, 48, 52, and 56 stand rejected under 35 U.S.C. §103(a) over U.S. Patent No. 5,919,147 to Jain ("Jain") in view of U.S. Patent No. 5,010,892 to Colvin et al. ("Colvin"), U.S. Patent No. 6,712,771 to Haddock et al. ("Haddock"), U.S. Patent No. 6,033,359 to Doi ("Doi"), and U.S. Patent No. 6,450,977 to Baxter-Jones ("Baxter-Jones").

c) Claims 46, 49, 50, 53, 54, and 57 stand rejected under 35 U.S.C. §103(a) over Jain in view of Colvin, Haddock, Doi, and Baxter-Jones and further in view of U.S. Patent No. 4,972,584 to Baumann ("Baumann").

7. ***Argument.***

a) Rejection of Claims 5, 12, and 41 under 35 U.S.C. §112, ¶1

The Examiner rejects Claims 5, 12, and 41 for allegedly failing to comply with the written description requirement because "the original disclosure does not appear to support inward facing surfaces of the legs in the embodiment of figures 14-18 being in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit." Applicant disagrees with this rejection, as Claims 5, 12, and 41 are supported by the specification. According to MPEP §2163, the criteria for determining whether the written description requirement is satisfied is that "each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure." In addition, "the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." See MPEP §2163.03.

The present application discloses on page 9, lines 14-18 that the legs (250, 300) are configured to lay substantially flush to one another when constrained by the exterior conduit

(130). With respect to the embodiment described in FIGS. 14-18, page 10, lines 23-26 of the present application discloses that "when the measurement assembly is retracted, the legs are relaxed and reside adjacent to one another so that the legs may be retracted within the exterior conduit." Moreover, the only difference between the embodiments shown in FIGS. 1-13 and FIGS. 14-18 is that the distal ends of the legs are coupled together in FIGS. 14-18, and the specification does not disclose otherwise. In fact, FIG. 4 (with the distal ends of the legs not coupled) and FIG. 15 (with the distal ends of the legs coupled) are practically identical, and the reference numbers used to identify the embodiment of FIGS. 14-18 are the same as the embodiment shown in FIGS. 1-13. In addition, FIG. 18 of the present application shows the legs displaced from the exterior conduit, wherein portions of the legs proximate to the proximal and distal ends are in flush contact, such that as the legs are retracted into the exterior conduit, the legs would lie flush with one another along their entire length. Clearly, the only difference between the embodiments is that the distal ends of the legs are either coupled or not coupled together. Thus, although not explicitly disclosed, the present application implicitly and/or inherently provides with *reasonable clarity* to one of ordinary skill in the art that the legs are configured to extend flush to one another when constrained within the exterior conduit, regardless of whether the legs are coupled at their distal ends or not. Therefore, Applicant respectfully submits that the rejection of Claims 5, 12, and 41 under §112, first paragraph, is overcome.

b) Rejection of Claims 1, 3-8, 10-24, 37, 39-42, 45, 48, 52, and 56 under 35 U.S.C. §103(a) over Jain in view of Colvin, Haddock, Doi, and Baxter-Jones

1) *The Cited References*

Jain discloses a vascular measuring device 10 including a sheath 22, a catheter 24, and a sensor 26, as shown in Figures 1-4. A proximal end 38 of the catheter includes graduated markings 42, while the distal end 40 supports the sensor 26. The sensor 26 includes several radially outwardly-biased filaments 44. When the catheter is retained within the sheath, the distal ends of the filaments bias outwardly to abut the interior of the sheath, as shown in Figure

2. When deployed from the sheath, the filaments of the sensor bias further outwardly to abut the interior of the blood vessel, as shown in Figure 3. In another embodiment, Jain discloses a different sensor 54, as shown in Figures 5 and 6. The sensor 54 includes a pair of outwardly-biased arcuate arm springs 56 and 58. These springs are in a "longitudinally flat position" when in a retracted position within the sheath 22.

Colvin discloses a measuring instrument 10 having a sleeve 12, a handle 14 and a flexible cable 16 positioned within the sleeve, as shown in Figures 1 and 2. At a distal end of the flexible cable is a bifurcated probe having a memory for an outwardly curved shape when extended from the sleeve. A scale 24 is correlated to the deployment of the probe and provides a diameter measurement of a lumen. Ends of the bifurcated probes of the flexible cable each include a rounded ball at their distal ends.

Haddock discloses a temperature sensing catheter. Figures 3A-3C of Haddock illustrate an embodiment of a "second hand-type structure" that includes fingers 302 that are slidably disposed within an outer sheath 300. The fingers include sensors 304 that are configured to expand outwardly to contact the inner wall of the vessel as the fingers are pushed out of the outer sheath. The sensors may be used to provide localized temperature or an estimate of the inner diameter of the vessel.

Doi discloses a length-measuring tool that includes strips 4 that are configured to spread outwardly via bendable portions 5, 6, 7 into a cross-shape. Each strip includes a scale 8 on a length-measuring section 9 that provides information regarding the size of a diseased part.

Baxter-Jones discloses a device for measuring a cervix that includes a hollow member 1104, an elongated member 1102, and a slidable indicator 1116. The device also includes a measuring scale 1118 and respective detents 1130. The slidable indicator is configured to slide along the elongated member and engage detents in order to provide a length of the cervix using the measurement scale.

2) Independent Claims 1, 7, 24, and 37

As indicated in the Brief Summary of Claimed Subject matter, each of independent Claims 1, 7, 24, and 37 recites a measurement assembly including at least two legs having distal and proximal ends and inward facing and lumen facing surfaces. The inward facing surfaces of

the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit. Thus, as shown in FIGS. 9 (side view) and FIG. 12 (end view), for example, each of the legs is flush along their entire length when the legs are positioned within the exterior conduit. In particular, FIG. 12 demonstrates that there may be four such legs in flush contact with one another according to one embodiment of the present invention.

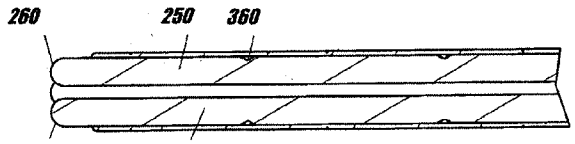


FIG. 9

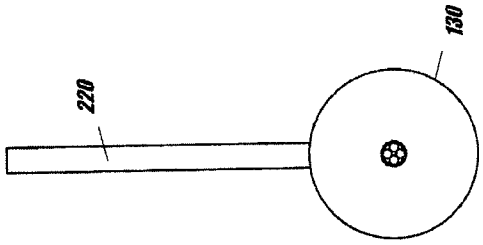


FIG. 12

Claims 1 and 37 further recite that the lumen facing surface of each of the legs includes a plurality of measurement markers, wherein the exterior conduit is configured to engage the measurement markers of the legs to provide an indication of a diameter of the target segment. Similarly, Claims 7 and 24 recite that the lumen facing surface of each of the legs includes a plurality of measurement markers that are configured to provide information regarding a diameter of the target segment and that the exterior conduit and measurement assembly are displaced relative to one another such that the exterior conduit engages the measurement markers of the legs to provide an indication of a diameter of the target segment. For example, FIG. 11 of the present application illustrates that the measurement markers (350) may be detents (360) that are configured to be engaged by a lip (170) extending from the outer sheath (130). Engagement of the detents and lip provides stability that facilitates accurate measurement calculations and ensures that the legs do not overshoot the maximum lumen measurement and damage the lumen tissue.

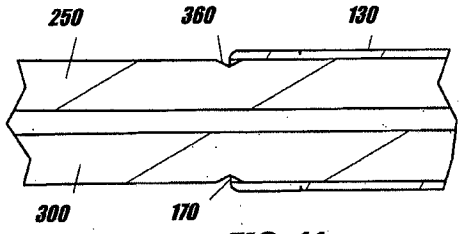


FIG. 11

3) The Rejection of Independent Claims 1, 7, 24, and 37 under 35 U.S.C. §103(a) is Overcome

Applicants submit that there is no teaching or suggestion to combine or modify the cited references to render independent Claims 1, 7, 24, and 27 obvious. In particular, Applicants submit that there is no motivation to combine Jain and Haddock and modify Jain to include inward facing surfaces of the legs that are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit, as recited by independent Claims 1, 7, 24, and 37. Moreover, Applicants submit that there is no teaching or suggestion to combine Jain, Doi, and Baxter-Jones and modify Jain to include an exterior conduit that is configured to engage the measurement markers of the legs to provide an indication of a diameter of the target segment, as recited by independent Claims 1, 7, 24, and 37.

In order to properly combine references, a teaching or motivation to combine the references is essential. *In re Fine*, 337 F.2d 1071, 1075 (Fed. Cir. 1988). In fact, the Court of Appeals for the Federal Circuit has stated that, "[c]ombining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability -- the essence of hindsight." *In re Dembiczak* , 175 F.3d 994 (Fed. Cir. 1999). Although the evidence of a suggestion, teaching, or motivation to combine the references commonly comes from the prior art references themselves, the suggestion, teaching, or motivation can come from the knowledge of one of ordinary skill in the art or the nature of the problem to be solved. *Id.* In any event, the showing must be clear and particular and "[b]road conclusory statements regarding the teaching effect of multiple references, standing alone, are not 'evidence.'" *Id.* Although the Court in *KSR Int'l Co.*

v. Teleflex Inc. found that the teaching, suggestion, and motivation test should not be rigidly applied, some teaching, suggestion, or motivation and a reasonable expectation of success are needed in order to properly combine references. *See* MPEP §2143 (citing *KSR*, 550 U.S. ___, 82 USPQ2d, 1385 (2007)).

The Examiner acknowledges that Jain does not disclose inward facing surfaces that are in flush contact with one another from the distal ends to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit, as recited by Claims 1, 7, 25, and 31. Instead, the Examiner relies on Haddock for Jain's shortcomings, wherein Haddock discloses fingers (302) that are slidably disposed within an outer sheath (300) and that are configured to expand outwardly to contact the inner wall of the vessel as the fingers are pushed out of the outer sheath. However, as shown below in FIG. 2 of Jain, the sensor (26) includes wire filaments (44) that are attached to the distal end (40) of the catheter (24) and are positioned within a sheath (22).

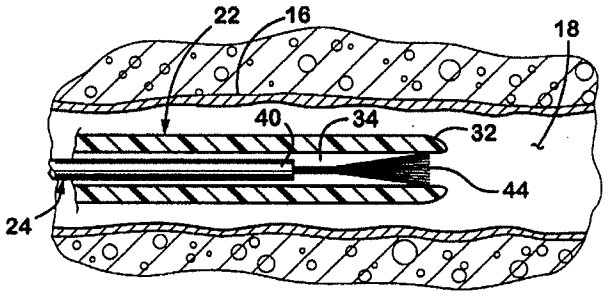


Fig. 2

Moreover, FIG. 2 of Jain shows that the ability of the wire filaments to lie flush to one another is limited by the diameter of the catheter within the sheath which is significantly larger than the wire filaments. In fact, FIG. 2 shows that the wire filaments fan outwardly within the sheath, and Jain explicitly discloses that the wire filaments fan outwardly in a conical fashion but are restrained from fully doing so by the sheath and shown by FIG. 2 (col. 3, lines 16-18 and 20-23). Moreover, Jain discloses that the ends of the wire filaments may be rounded to prevent them from puncturing the tissue (col. 3, lines 7-10). Haddock discloses a much different arrangement as shown in FIG. 3C, wherein the inner structure has integrally formed fingers (310) that are

cantilevered and positioned within the sheath (300). The fingers include sensors (304, 312) on their outer surfaces that are configured to contact the inner lumen.

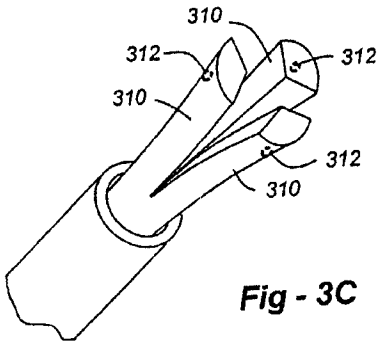


Fig - 3C

Thus, Applicants submit that there is no teaching or suggestion to modify the wire filaments of Jain to include the configuration of fingers disclosed by Haddock. Namely, Jain clearly shows that the wire filaments are biased outwardly within the sheath and that the configuration of the catheter and wire filaments would prevent the filaments from lying flush to one another along their entire lengths as shown in FIG. 2 of Jain. Although Haddock discloses that the fingers may lie flush to one another, Haddock illustrates that the fingers are integrally formed from a cylindrical structure. In addition, Haddock discloses that the fingers include sensors on their outer surfaces that are configured to contact the tissue, while Jain discloses that rather than the outer surfaces, the distal ends of the wire filaments contact the tissue to measure the diameter of the lumen. Therefore, there is no teaching or suggestion to modify Jain to include wire filaments that have their inward facing surfaces that lie in flush contact with one another between their proximal and distal ends and independent Claims 1, 7, 25, and 31 are distinguishable from the cited references for at least this reason.

Furthermore, the Examiner acknowledges that Jain does not disclose "that the lumen facing surface of each of the legs includes a plurality of measurement markers, and that the exterior conduit is configured to engage the measurement markers." However, the Examiner contends that Doi discloses measurement markers (8) on the lumen facing surface of the legs (3) and that Baxter-Jones discloses an exterior conduit (1116) that is configured to engage measurement markers or detents (1130) of the legs to provide an indication of a diameter of the target segment.

Baxter-Jones simply discloses a slidable indicator that slides over a single elongated member for determining length, and Applicants fail to appreciate why one of ordinary skill in the art would look to Baxter-Jones to solve the problem of measuring the diameter of the lumen. In this regard, the devices of Jain and Doi may be used to measure a diameter of a target segment using radially expandable legs, while the device of Baxter-Jones is employed to measure the length of a cervix using an axially displaceable measurement indicator. Thus, these references are used for entirely different purposes and function in entirely different manners such that one of ordinary skill in the art would not have been motivated to modify Jain in light of the teachings of Doi and Baxter-Jones.

Furthermore, both Jain and Doi fail to remotely disclose or suggest an exterior conduit that is configured to engage measurement markers defined on the lumen-facing surfaces of a plurality of legs. In this regard, the scales or alleged measurement markers of Doi are not configured to bend or otherwise engage an outer exterior conduit but, rather, are *painted* on the outer surface of each strip so that the scales are disposed within a visual field that is viewable with an observation optical system of the endoscope (see col. 3, lines 12-14 and 49-53). The wire filaments of Jain do not include measurement markers at all. Thus, Applicants fail to appreciate the motivation to modify the visual indicators of Doi and the wire filaments of Jain to include measurements markers that can be engaged by an exterior conduit in light of Baxter-Jones and believe that suggest a motivation is lacking.

Applicants submit that the Examiner is simply picking and choosing elements from each of the cited references and is using impermissible hindsight to arrive at the claimed invention. Therefore, there is no motivation or suggestion to modify Jain in light of any of the remaining cited references to include an exterior conduit that is configured to engage legs having measurement indicators on their lumen-facing surfaces in order to determine a diameter of a target segment, as recited by independent Claims 1, 7, 24, and 31.

Accordingly, Applicants submit that the rejection of independent Claims 1, 7, 24, and 37 under 35 U.S.C. §103(a) is overcome. The remaining dependent claims depend from and further patentably distinguish Claims 1, 7, 24, and 37 and are also allowable for at least those reasons discussed above.

4) Dependent Claims 45, 48, 52, and 56 are Separately Patentable

Although Applicants submit that each of the dependent claims are allowable for at least those reasons discussed above for a respective independent claim, Applicants submit that several of the dependent claims are further distinguishable from the cited references. For example, none of the cited references teaches or suggests dependent Claims 45, 48, 52, and 56, which recite that the measurement markers of the legs comprise detents defined therein.

In order to overcome Jain's shortcomings, the Examiner relies on Baxter-Jones as disclosing Claims 45, 48, 52, and 56, which recite that the measurement markers of the legs comprise detents defined therein. Although Baxter-Jones discloses detents (1130), the detents are not defined in the elongated member (1102) but, rather, *project outwardly* from the outer surface of the elongated member. Page 10, lines 5-6 of the present application discloses that the measurement markers may be "carved into the legs so as to form detent or lip catches," which is nowhere taught or suggested by Baxter-Jones or any of the remaining cited references. Therefore, none of the cited references, taken alone or in combination, teaches or suggests Claims 45, 48, 52, and 56.

c) The Rejection of Dependent Claims 46, 49, 50, 53, 54, and 57 under 35 U.S.C. §103(a) is Overcome

Although Applicants submit that each of the dependent claims are allowable for at least those reasons discussed above for a respective independent claim, Applicants submit that several of the dependent claims are further distinguishable from the cited references. For example, none of the cited references teaches or suggests dependent Claims 46, 49, 50, 53, 54, and 57, which are directed to engagement of a lip on the exterior conduit with detents on the legs.

In this regard, Applicants submit that Baumann is non-analogous art for purposes of an obviousness rejection under 35 U.S.C. § 103(a). In particular, "Any analogous or pertinent prior art plays a role in the determination of the patentability of the claims at the time of invention." *Beckson Marine, Inc. v. NFM, Inc.*, 292 F.3d 718, 726 (Fed. Cir. 2002). A prior art reference is analogous if the reference is in the field of applicant's endeavor or, if not, the reference is

reasonably pertinent to the particular problem with which the inventor was concerned. *In re Oetiker*, 977 F.2d 1443, 1446 (Fed. Cir. 1992).

In this vein, Baumann is directed to a haircutting and trimming device that is clearly non-analogous and not pertinent to one of ordinary skill in the art for measuring a lumen or any other target segment within a patient. Haircutting and trimming devices are not "reasonably pertinent" to solving the problem of measuring the lumen or a target segment of a patient. Although Baumann discloses that the device may be adjusted to *vary the length of hair that is cut*, there is simply no reason why this particular feature would be applicable to devices that are used in the human body or for measuring the anatomy. Baumann is not even used to measure the length of the hair but, instead, provides a means to incrementally adjust the length of hair being cut such that there is not even the pertinence of obtaining a measurement. Applicants fail to appreciate the relevance of "cutlery" devices to medical devices used to determine a measurement within the human body and submit that Baumann is non-analogous art and should not be relied upon as prior art against the claimed invention.

Furthermore, Applicants respectfully submit that there is no motivation to modify any of the cited references in light of Baumann to include a lip extending from an inner surface of an exterior conduit that engages detents defined in the legs. In this regard, Baumann is in no way related to obtaining a measurement as described above, and one of ordinary skill in the art would not have been motivated to modify any of the remaining cited references in light of Baumann. Furthermore, the detents of Baxter-Jones are not defined within the legs such that one of ordinary skill in the art would not look to the lip (58) described by Baumann configured to engage notches (49) for use with the slidable indicator of Baxter-Jones. Therefore, Applicants respectfully submit that none of the cited references, taken alone or in combination, teaches or suggests Claims 46, 49, 50, 53, 54, and 57.

In any event, even if Baumann is erroneously combined with Jain and the remaining cited references, Applicants respectfully disagree that the combination renders Claims 46, 49, 50, 53, 54, and 57 obvious. Claims 46, 49, 53, and 57 recite that the exterior conduit comprises inner and outer surfaces, wherein the distal end of the exterior conduit comprises a lip protruding from the inner surface that is configured to engage the detents defined in the legs. Claims 50 and 54

recite that the method further includes measuring a diameter of the lumen by displacing the exterior conduit and measurement assembly relative to one another such that the lip engages a detent defined in each of the legs. The Examiner acknowledges that "Jain as combined with Colvin et al., Haddock et al., Doi, and Baxter-Jones do not teach that the distal end of the exterior conduit comprises a lip protruding from the inner surface that is configured to engage the detents." Instead, the Examiner relies on Baumann as teaching this particular configuration.

Applicants submit that Baumann does not teach or suggest that the distal end of the exterior conduit comprises a lip protruding from the inner surface that is configured to engage the detents defined in the legs. The Examiner finds that the outer end (57) is a detent that extends from an exterior conduit. However, as shown in FIGS. 6 and 7, Baumann does not disclose that the inner surface of the wall (54) or alleged exterior conduit includes a lip extending from its inner surface. Rather, a detent lever (52) is pivotally attached to the outer surface of the wall about pivot (53) such that the alleged inner surface of the wall does not include a lip protruding therefrom.

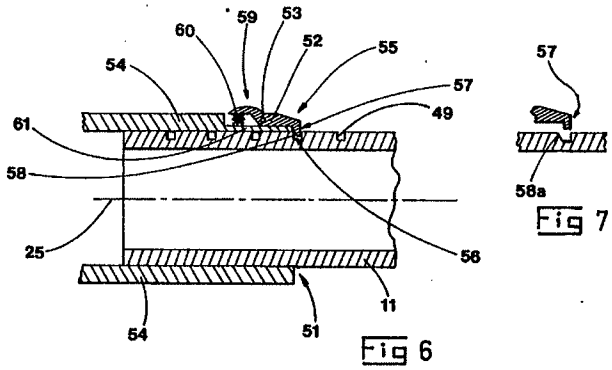


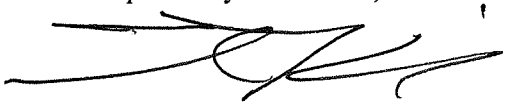
Fig 6 Fig 7

Nor is there any motivation to modify Baumann to include a lip protruding from the inner surface of the wall considering the functionality of the detent lever to adjust the length of hair to be cut would be compromised if this was the case. Therefore, neither Baumann, nor any of the remaining cited references, teaches or suggests Claims 46, 49, 50, 53, 54, and 57.

CONCLUSION

For the above reasons, it is submitted that the rejections of the pending claims are erroneous and reversal of the rejections is respectfully requested. A Claims Appendix containing a copy of claims involved in the appeal, an Evidence Appendix, and a Related Proceedings Appendix are attached.

Respectfully submitted,



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Claims Appendix.

1. (Previously Presented) A device for measuring a target segment of a lumen of a patient so as to select a suitable interventional prosthesis, the device comprising:

an exterior conduit longitudinally extending between proximal and distal ends, the exterior conduit having measurement markers formed on a portion thereof configured to provide information regarding a length of the target segment;

an interior conduit longitudinally extending between proximal and distal ends, disposed within the exterior conduit, and displaceable with respect to the exterior conduit, the interior conduit having a depth marking mechanism visible through a portion of the exterior conduit;

a measurement assembly comprising at least two legs having distal and proximal ends and inward facing and lumen facing surfaces wherein the inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit, the legs coupled with each other proximal the distal ends thereof, the measurement assembly also coupled about the distal end of the interior conduit, wherein the lumen facing surface of each of the legs includes a plurality of measurement markers, and wherein the exterior conduit is configured to engage the measurement markers of the legs to provide an indication of a diameter of the target segment;

a handle operatively connected with the measurement assembly, the handle comprising a means for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open configuration.

2. (Cancelled)

3. (Previously Presented) The device of claim 1, wherein when the measurement assembly is moved distally in relation to the exterior conduit, the legs form an acute angle with respect to one another.

4. (Original) The device of claim 3, wherein the measurement assembly further comprises a third leg.

5. (Previously Presented) The device of claim 1, wherein the distal ends of the legs are coupled together, wherein measurement of the target segment takes place between the distal and proximal ends of the legs.

6. (Previously Presented) The device of claim 1, wherein the handle further comprises a measurement indicator, wherein target lumen dimensions are calculated based on the relative distance the handle travels along the continuum between a first and second handle location.

7. (Previously Presented) A method of measuring a target segment of a lumen of a patient so as to select a suitable interventional prosthesis, the method comprising:

providing a measuring device having an exterior conduit longitudinally extending between proximal and distal ends, the exterior conduit having measurement markers formed on a portion thereof configured to provide information regarding a length of the target segment; an interior conduit longitudinally extending between proximal and distal ends, disposed within the exterior conduit, and displaceable with respect to the exterior conduit, the interior conduit having

a depth marking mechanism visible through a portion of the exterior conduit; a measurement assembly comprising at least two legs having distal and proximal ends and inward facing and lumen facing surfaces wherein the inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit, the legs coupled with each other proximal the distal ends thereof, the measurement assembly also coupled about the distal end of the interior conduit, wherein the lumen facing surface of each of the legs includes a plurality of measurement markers that are configured to provide information regarding a diameter of the target segment; a handle operatively connected with the measurement assembly, the handle comprising a means for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open configuration;

introducing the device into an appropriate anatomical orifice of a patient;

delivering the device adjacent a target segment of a lumen within the patient;

measuring the length of the target segment of the lumen within the patient; and

displacing the exterior conduit and measurement assembly relative to one another such that the exterior conduit engages the measurement markers of the legs to provide an indication of a diameter of the target segment.

8. (Original) The method of claim 7, wherein the device further comprises an optical scope operatively coupled therewith, such that the measuring step is accomplished using the optical scope.

9. (Cancelled)

10. (Previously Presented) The method of claim 7, wherein when the measurement assembly is moved distally in relation to the exterior conduit, the legs form an acute angle with respect to one another.

11. (Original) The method of claim 10, wherein the measurement assembly further comprises a third leg.

12. (Previously Presented) The method of claim 7, wherein the distal ends of the legs are coupled together, wherein measurement of the target segment takes place between the distal and proximal ends of the legs.

13. (Previously Presented) The method of claim 7, wherein the handle further comprises a measurement indicator, wherein target lumen dimensions are calculated based on the relative distance the handle travels along the continuum between a first and second handle location.

14. (Original) The method of claim 7, further comprising the step of measuring the diameter of the target segment of the lumen within the patient.

15. (Previously Presented) The method of claim 14, wherein the diameter measuring step comprises the step of actuating the handle along the continuum from the first closed configuration toward the second open configuration until the legs of the measurement assembly come in contact with the target segment of the lumen and calculating the diameter as a function of the number of leg measurement markings distal the exterior conduit.

16. (Original) The method of claim 14, wherein the target segment of the lumen is stenotic.

17. (Previously Presented) The method of claim 7, wherein the device further comprises an optical scope operatively coupled therewith, such that the measuring step is accomplished using the optical scope to view placement of the measurement assembly.

18. (Original) The method of claim 16, further comprising the step of measuring the length of the stenosis.

19. (Previously Presented) The method of claim 18, wherein the delivering step further comprises the step of positioning the distal end of the exterior conduit distal the stenosis.

20. (Previously Presented) The method of claim 19, wherein the measurement assembly is opened and placed distal the stenosis such that the exterior conduit is retracted and the stenosis length measurement is a function of the distance the exterior conduit is retracted proximally.

21. (Original) The method of claim 18, wherein the stenosis length measuring step comprises the step of actuating the handle along the continuum from the first closed configuration toward the second open configuration until the legs of the measurement mechanism come in contact with the target segment of the lumen and calculating the length as a function of the distance between the first handle position and the current point of the handle along the continuum.

22. (Original) The method of claim 16, further comprising the step of measuring the height of the stenosis.

23. (Original) The method of claim 22, further comprising the step of measuring the length of the stenosis.

24. (Previously Presented) A method of measuring a target segment of a lumen of a patient so as to select a suitable interventional prosthesis, the method comprising:

providing a measuring device having an exterior conduit longitudinally extending between proximal and distal ends, the exterior conduit having measurement markers formed on a portion thereof configured to provide information regarding a length of the target segment; an interior conduit longitudinally extending between proximal and distal ends, disposed within the exterior conduit, and displaceable with respect to the exterior conduit, the interior conduit having a depth marking mechanism visible through a portion of the exterior conduit; a measurement assembly comprising four legs having distal and proximal ends and inward facing and lumen facing surfaces wherein the inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to proximal ends of the legs when the measurement assembly is closed within the exterior conduit, the legs coupled with each other proximal the distal ends thereof, the measurement assembly also coupled about the distal end of the interior conduit, wherein the lumen facing surface of each of the legs includes a plurality of measurement markers that are configured to provide information regarding a diameter of the target segment; a handle operatively connected with the measurement assembly, the handle comprising a means

for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open configuration;

introducing the device into an appropriate anatomical orifice of a patient;

delivering the device adjacent a target segment of a lumen within the patient; and

measuring the diameter of the target segment of the lumen within the patient, wherein measuring a diameter of the target segment comprises displacing the exterior conduit and measurement assembly relative to one another such that the exterior conduit engages the measurement markers of the legs.

25-36. (Cancelled)

37. (Previously Presented) A device for measuring a target segment of a lumen of a patient so as to select a suitable interventional prosthesis, the device comprising:

an exterior conduit longitudinally extending between proximal and distal ends, the exterior conduit having measurement markers formed on a portion thereof configured to provide information regarding a length of a target segment;

an interior conduit longitudinally extending between proximal and distal ends, disposed within the exterior conduit, and displaceable with respect to the exterior conduit;

a measurement assembly comprising a plurality of legs having distal and proximal ends and inward facing and lumen facing surfaces wherein the inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit, the legs coupled with each other proximal the distal ends thereof, the measurement assembly also coupled about the

distal end of the interior conduit, wherein the lumen facing surface of each of the legs includes a plurality of measurement markers, and wherein the exterior conduit is configured to engage the measurement markers of the legs to provide an indication of a diameter of the target segment;

a handle operatively connected with the measurement assembly, the handle comprising a means for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open configuration.

38. (Cancelled)

39. (Previously Presented) The device of claim 37, wherein when the measurement assembly is moved distally in relation to the exterior conduit, the legs form an acute angle with respect to one another.

40. (Original) The device of claim 39, wherein the measurement assembly comprises four legs.

41. (Previously Presented) The device of claim 37, wherein the distal ends of the legs are coupled together, wherein measurement of the target segment takes place between the distal and proximal ends of the legs.

42. (Previously Presented) The device of claim 37, wherein the handle further comprises a measurement indicator, wherein target lumen dimensions are calculated based on the relative distance the handle travels along the continuum between a first and second handle location.

43. (Cancelled)

44. (Cancelled)

45. (Previously Presented) The device of claim 1, wherein the measurement markers of the legs comprise detents defined therein.

46. (Previously Presented) The device of claim 45, wherein the exterior conduit comprises inner and outer surfaces, and wherein the distal end of the exterior conduit comprises a lip protruding from the inner surface that is configured to engage the detents defined in the legs.

47. (Cancelled)

48. (Previously Presented) The method of claim 7, wherein the measurement markers of the legs comprise detents defined therein.

49. (Previously Presented) The method of claim 48, wherein the exterior conduit comprises inner and outer surfaces, and wherein the distal end of the exterior conduit comprises a lip protruding from the inner surface that is configured to engage the detents defined in the legs.

50. (Previously Presented) The method of Claim 49, further comprising measuring a diameter of the lumen by displacing the exterior conduit and measurement assembly relative to one another such that the lip engages a detent defined in each of the legs.

51. (Cancelled)

52. (Previously Presented) The method of claim 24, wherein the measurement markers of the legs comprise detents defined therein.

53. (Previously Presented) The method of claim 52, wherein the exterior conduit comprises inner and outer surfaces, and wherein the distal end of the exterior conduit comprises a lip protruding from the inner surface that is configured to engage the detents defined in the legs.

54. (Previously Presented) The method of Claim 53, wherein measuring a diameter of the lumen comprises displacing the exterior conduit and measurement assembly relative to one another such that the lip engages a detent defined in each of the legs.

55. (Cancelled)

56. (Previously Presented) The device of claim 37, wherein the measurement markers of the legs comprise detents defined therein.

57. (Previously Presented) The device of claim 56, wherein the exterior conduit comprises inner and outer surfaces, and wherein the distal end of the exterior conduit comprises a lip protruding from the inner surface that is configured to engage the detents defined in the legs.

Evidence Appendix.

None.

Related Proceedings Appendix.

None.